

**REMARKS**

This is in response to the Official Action mailed March 20, 2006.

Claim 16 and the specification have been amended to correct minor typographical errors. No new matter is believed to have been added from these amendments.

Initially, Applicants thank the Examiner for the initialed PTO-1449 forms corresponding to the Information Disclosure Statements dated May 15, 2002 and July 24, 2002, that were included with the Official Action.

Turning now to the sole rejection, claims 1-36 have been rejected under 35 U.S.C. § 102(e) over U.S. Patent No. 6,685,678 (Evans). The rejection is respectfully traversed.

Generally, as recited in claim 1, the present invention is directed to a medical device for administration of a drug. The device comprises a source of a drug to be administered to a patient, a holder for the source, and a tracking code operatively associated with the source.

In accordance with claims 8 and 12, the source may be a syringe or IV port, the holder may be a syringe or port label cradle, and the tracking code is affixed to at least one of the cradle and the source.

As recited in claims 16 and 27, the present invention is also directed to methods for tracking data associated with a medical device adapted for administration of a drug to a patient. In claim 16, the method involves providing a source of a drug to be administered to a patient, associating a tracking code to the source, and providing data associated with the drug, and storing data in association with the tracking code. Claim 27 recites similar steps as claim 16, but with the additional step of retrieving the data from storage in response to the tracking code. Also, claim 27 includes the additional limitations of the tracking code being in the form of a bar code and the tracking code being on a label affixed to either the

source or a cradle holding the source. In addition, instead of the step of just providing data associated with a drug, claim 27 recites the step of identifying data associated with the drug and the patient.

Further, as recited in claim 31, the present invention is directed to a system for tracking data associated with a medical device adapted for the administration of a drug to a patient. The system comprises a medical device adapted for the administration of a drug to a patient and a storage and retrieval device for storing and retrieving data related to the drug. The medical device includes a cradle, a source of a drug to be administered to a patient attached to the cradle, and a tracking code associated with at least one of the cradle and the source.

As noted above, an important feature of the medical device, methods and system of the present invention is the incorporation of or use of a tracking code for tracking data associated with a medical device that administers drugs to a patient.

In the Official Action, the Patent Office has apparently taken the position that the bar code disclosed in column 2, lines 5-16, of Evans is equivalent to the tracking code of the present invention. Applicants respectfully disagree.

The tracking code of the present invention, as described in columns [0007] - [0009] of the specification, relates to a code (e.g., number) associated with a medical device for the purpose of tracking events pertaining to the medical device with which it is associated. For example, data relating to the activities of a particular device, such as drug preparation, drug inventory, drug dispensing, drug administration, drug charge and drug credit, may be recorded and related to a unique tracking code. In addition, each time an activity occurs, a log is created relating the patient to the

specific drug involved and all information contained in respective patient and drug databases. Thus, through such a log, the tracking code acts as a unique identifier that enables individual unit doses to be tracked. In this manner, this present invention's use of a tracking code is similar or comparable to the use of a tracking code to track or monitor the delivery of packages.

Initially, Applicants wish to clarify that although the tracking code of the present invention is a code (e.g., number) that may be in the form of a bar code, the tracking code is not limited to a bar code form and may be in other forms as well. For example, the tracking code of the present invention may be human-readable or emitted as a signal or part of a signal from a Radio Frequency Identification (RFID) tag, and need not be in a form optically readable by a scanner (such as a bar code).

Regardless of form, as made clear in paragraph [0028], the bar code disclosed in Evans, is not the same as the tracking code of the present invention. As explained in paragraph [0028], "in addition to the tracking code, other bar coded information may be provided on the label..." Among other items of information listed in paragraph [0028], the other bar coded information may be, for example, a patient's name. As disclosed in Evans, its bar code, described as a "patient identifier," is merely used to relay patient information to ensure that the right drug is matched with the right patient. Instead of simply relaying information to ensure a correct match of a specific drug with a patient, the tracking code and the tracking system of the present invention allow individual drug unit doses to be tracked at all times, regardless of the location of or activity involving the drug unit dose. For example, as described in paragraphs [0029] - [0036], the tracking code allows an individual unit dose to be tracked from location to location and department to department, from its

preparation at a hospital pharmacy to administration of its contents by a physician in an operating room to its return to the pharmacy once its contents have been dispensed. However, there is no disclosure or suggestion in Evans of any tracking capability, functionality or use for its bar code. Therefore, Applicants submit that the bar code in Evans constitutes at most "other bar coded information," and cannot be considered a tracking code. In this regard, there is no disclosure or suggestion in Evans of associating a tracking code with a drug dispensing medical device or a method or system that uses a tracking code for tracking data associated with a drug dispensing medical device.

Accordingly, for all of the foregoing reasons, withdrawal of the § 102(e) rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: May 12, 2006

Respectfully submitted,

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